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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,532	11/01/2000	Dean L. Kamen	1062/C39	1972

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BROMBERG & SUNSTEIN LLP
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BOSTON, MA 02110-1618

EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 03/04/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/703,532

Applicant(s)

KAMEN ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated January 8, 2004. Claims 1-14 are pending. The amendments to the drawings are acknowledged.

Response to Arguments

1. Applicant's arguments filed January 8, 2004 have been fully considered but they are not persuasive.

Applicant argues, "merely because the Examiner contends it is necessary to control the flow does not mean that it is obvious to: a) have the control be a valve; b) have the control be a flow valve for metering in the endarterectomy instrument itself that can be operated directly by the surgeon during surgery. An instrument with a control valve in the handle provides significant advantages over conventional on/off metering done remote from the surgical site by someone other than the surgeon in the act of performing surgery."

Applicant's attention is first drawn their submission that on/off metering is conventional. The examiner further asserts that valves are extraordinarily well-known flow control/metering devices. In a reasonably broad sense metering can even encompass on/off flow control, as even admitted by applicant, where valves, including on/off as well as variable control are extraordinarily well known.

Applicant's attention is directed to the additional cited references below, which are just merely a few of the plethora of references demonstrating the use of

valves for flow control. Thus, applicant has failed to include structural features to define over the prior art rejection.

Regarding applicant's argument directed toward the rejection over Newman et al. in view of Matsui et al., applicant's arguments have been considered but the claim language does not preclude the combination. Applicant argues a balloon structure, which is not a consideration of the claim. Further, applicant argues, intended use. The claim is directed to a shaft, a head, a handle, and grasping device. There is no limitation or requisition for any intended use. Structural features have not been provided that define the invention in the environment and demonstrate their criticality/necessity for that environment that exclude other environments.

Regarding applicant's arguments directed toward the rejection over Newman et al. in view of Deaton et al., applicant argues Deaton et al. do not teach a grasping device that does not have a retracted configuration. However, Deaton et al. clearly teach a flexible member (100) that tends to flex outward. When disposed in a vessel or tube will be **retracted and grasp** toward the outside of the vessel or tube.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713.

Regarding claim 1, Newman et al. disclose an endarterectomy surgical instrument having a shaft (such as 30) having proximal and distal ends, as seen in figure 1; a head (10) coupled to the distal end of the shaft, the head having an endoscope port (12) and at least one fluid port (14); a handle (such as 28) coupled to the proximal end of the shaft, the handle including *a gas supply port in fluid communication with the at least one gas port on the head*, as recited in column 3, lines 49-67 and column 4; and a locking mechanism for retaining an endoscope, as recited in column 5, lines 1-14. However, Newman et al. do not explicitly recite a flow valve for metering flow of gas between the gas supply port and the at least one fluid port on the head. On the other hand it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include a flow valve for metering the flow of gas, for it is **necessary** to control the flow of gas and a valve is the well known method to do so.

Regarding claim 2, Newman et al. disclose a saline solution inlet coupled to the handle for coupling a flow of saline solution to the at least one fluid port on the head, as recited in column 5, lines 3-7.

Regarding claim 3, Newman et al. disclose a fluid connection of the handle to the head of the shaft is provided through a first lumen, as recited in column 3, line 49-column 5 and seen in figure 1.

Regarding claim 4, Newman et al. disclose an endoscope (20) for providing optical coupling through a second lumen between the distal and proximal ends of the shaft, as recited in column 4 and seen in figures 1 and 3.

Regarding claim 5, Newman et al. disclose a fluid connection of the handle to the head of that shaft that is provided through a first lumen (14), further having an endoscope (20) for providing optical coupling through a second lumen (12) between the distal and proximal ends of the shaft, as recited in column 4 and seen in figures 1 and 3.

Regarding claim 6, Newman et al. disclose a first lumen that is identical to the second lumen, which appear to be identical in figure 1.

4. Claims 7-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713 in view of Matsui et al. in US Patent No. 6,352,503.

Newman et al. disclose the invention as applied to claims 1-6 above.

Regarding claim 7, Newman et al. do not recite a grasping device having a retracted configuration and a deployable configuration wherein the grasping device extends away

from the head in the deployed configuration. On the other hand, Matsui et al. a grasping device (such as 2) having a retracted configuration and a deployable configuration wherein the grasping device extends away from the head in the deployed configuration, as recited in columns 7-8 and seen in figures 1-7. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include a grasping device for the purpose of blockage removal.

Regarding claim 8, the modification of Newman via the teachings of Matsui would yield a deployment control disposed on the handle of the instrument and in mechanical communication with the grasper device.

Regarding claim 9, it would be further obvious to have a grasper device that is a barb.

Regarding claim 10, it would also be obvious to have a grasper device that is a hook.

Regarding claim 11, Matsui teach a deployment control that is a slide, wherein the graspers are slidable into place.

Regarding claim 13, the subject matter has been covered in that stated above.

Regarding claim 14, a method for performing endarterectomy for removing an obstruction from a blood vessel via inserting the endarterectomy surgical instrument of

claim 1 though a single incision in a blood vessel; providing fluid through the at least one fluid port of the head for separating intima media layers of the artery surrounding the blockage; grasping the blockage with a grasping device at the distal end of the endarterectomy instrument and removing the blockage though the incision would also be obvious.

5. Claims 7 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713 in view of Deaton et al. in US Patent No. 6,565,583.

Newman et al. disclose the invention as applied to claim 1.

Regarding claim 7, Newman et al. do not explicitly recite a grasping device having a retracted configuration and a deployed configuration wherein the grasping device extends away from the head in the deployed configuration. On the other hand, Deaton et al. teach a grasping device (such as 100) having a retracted configuration and a deployed configuration wherein the grasping device extends away from the head in the deployed configuration, as recited in columns 5-8 and seen in figures 1-8. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include the grasping device of Deaton et al. for the purpose of blockage removal.

Regarding claim 11, Deaton et al. teach communication between the deployment control and the grasping device that includes a control wire having a first wire end and a

second wire end where the first wire is connected to the grasping device and the second end connected to the deployment control, as recited in column 12, for example. Therefore, it would be obvious to further modify the invention of Newman et al. to include a control wire for the purpose of deployment control.

Regarding claim 12, the subject matter is covered in that stated above.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/161,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,630,783 (column 5, lines 55-67 and column 6, lines 1-31, Figures 2-6); US Patent No. 5,476,450 (column 7 and Figure 1); US Patent No. 4,729,763 (column 4); US Patent No. 4,445,509; and US Patent No. 4,258,721 (columns 3 and 4 and figures).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

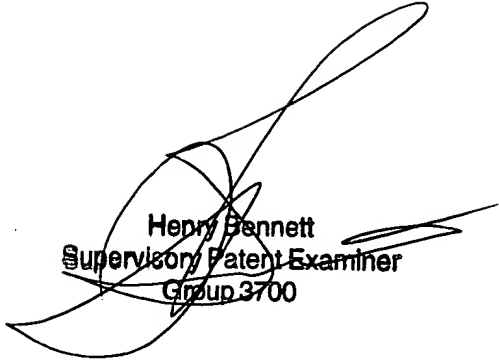
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/703,532
Art Unit: 3743

Page 10

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